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INTRODUCTION

Two ready-to-use standard parenteral nutrition (PN) have been developed for the first days of life of premature and neonates, together with syringes of lipid emulsion with or without vitamins.

FORMULATIONS

Ready-to-use PN		AA ¹	D ²	Na	K	Ca	PO ₄	Heparin
		g		mmol				UI
PN Day 0 (D0)	For 100 ml	3	10.8	--	--	--	—	50
PN Day 1-4 (D1-4)	For 100 ml	3	10.8	2	1	1.1	0.86	50

Lipids	Lipids	Vitamins
Syringes	Lipofundin® ³	—
Syringes	Lipofundin® ³	Cernevit®

¹ Amino Acids (Vaminolact®) ² Dextrose

³ long-chain triglyceride and medium-chain triglyceride

METHODS

Physical stability :

- visual inspection
- particles size
- pH and osmolarity

Chemical stability (concentration range : 90%-110%)

- AA, vitamins A,E and C by HPLC
- Dextrose by spectrophotometry (enzymatic method, 340 nm)
- Na, K, Ca by ion specific electrodes, PO₄ by colorimetry
- Lipid peroxydation by Ferrix-Xylenol Orange method

Conditions :

- Carried out for 12 weeks
- Between 2-8°C (F)
- Between 25-30°C (RT)

RESULTS

Ready-to-use PN stability

Physical stability :



- pH 5.1

- Osmo.950 mosm/L



- pH 5.8

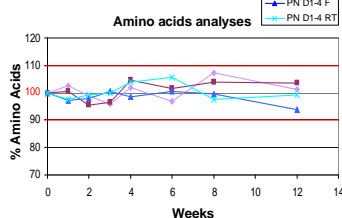
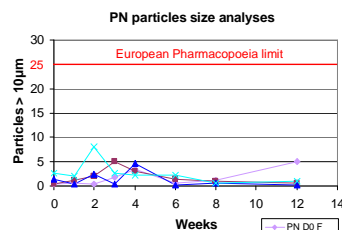
- Osmo.1000 mosm/L

PN in F remained limpid, whereas a brown coloration was observed in PN at RT after 3 weeks.

No precipitation for 12 weeks (RT and F)

Chemical stability :

All nutrients remained stable for 12 weeks of storage (F and RT).



Lipid emulsion stability

Physical stability :

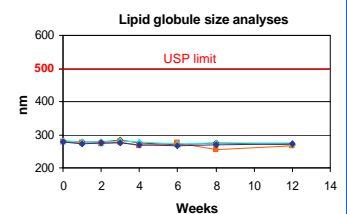


With vitamins



Without vitamins

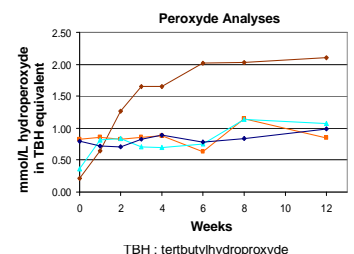
Creaming occurred after 3 weeks (F and RT, with and without vitamins) but mean droplet diameter and size distribution complied with the USP limits for 12 week.



Chemical stability :

Vitamin C : loss > 10% (F and RT) after 2 weeks

Vitamins A and E : remained stable for 2 weeks (F and RT)



CONCLUSION

Ready-to-use PN :

physically and chemically stable 12 weeks in the F or 2 weeks at RT.

Lipid emulsion syringes :

physically and chemically stable for 1 week in the F because of creaming.

The determined stability for the two ready-to-use standard PN and for lipid emulsion syringes allow their storage in wards. They can be used as soon as needed without any delay which is a major advantage over tailor-made PN.